REMARKS/ARGUMENTS

Reconsideration and allowance of the pending claims is respectfully requested in light of the remarks which follow. Claims 9-13, 15-22, and 41-52 have been canceled. Claim 8 has been amended. Support for the amendment of claim 8 may be found, for instance, in the specification at page 8, lines 19-25. Upon entry of this amendment, claims 8, 14, 23-40, and 53-54 will be pending.

Claim rejections under 35 U.S.C. § 112, first paragraph

Claims 8-41 and 54 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Applicants respectfully traverse.

In making this rejection, the Examiner has put forth a formula for determining the number of potential sequences that could be 95% identical to SEQ ID NO:2 and concludes that a large number of sequences is possible. Based on this allegedly large number of possible sequences, the Examiner concludes that "the skilled artisan would not have been able to envision a sufficient number of specific embodiments to describe the broadly claimed genus of polypeptides or polynucleotides having at least 95% identity to SEQ ID NO:2 or SEQ ID NO:1. Applicants respectfully traverse, at the very least, on the grounds that the Examiner has only stated one of the two ways in which a claimed genus of sequences can satisfy the written description requirement, and, as explained below, the pending claims conform to the second way in which the written description requirement can be satisfied.

The requirements for adequate written description of a chemical genus is set forth in *University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997). As described by the Federal Circuit in *Lilly*, "[a] description of a genus of cDNAs may be achieved by "recitation of a representative number of [species] . . . ***or*** a recitation of *structural features common* to members of the genus . . ." *Lilly*, 43 USPQ2d at 1406 (emphasis added).

In the present application, the genus of MRE11 polypeptides and nucleic acids is claimed by reference to shared structural features, *i.e.*, polypeptide sequences of SEQ ID NO:2

or nucleic acid sequences of SEQ ID NO:1. Claims 8 and 54 recite further structural features common to members of the genus, namely that they be at least 95% identical to SEQ ID NO:2 or SEQ ID NO:1, respectively.

Thus, Applicants have provided a description of both a reference amino acid or nucleotide sequence, as well as, the common structural feature of per cent identity of members of the genus. As required by the standard set forth in *Lilly*, these structural features are common to all of the members of the MRE11 genus, as claimed. The disclosure of the reference sequences of MRE11 along with a per cent identity, as well as a claimed enzymatic activity, would "clearly allow persons of skill in the art to recognize that [the Applicants] invented what is claimed." *See Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). Accordingly, the specification provides an adequate written description of the claimed genus of MRE11 protein and nucleic acid using structural/physical features as required by the court in *Lilly*. Under this aspect of the requirement as set forth in *Lilly*, the number of potential sequences is not relevant to an analysis of adequate written description as along as a description of structural features common to the genus is provided. As such, Applicants respectfully request withdrawal of this ground for rejection.

Claim rejections under 35 U.S.C. § 102(e)

Claims 8-12, 14-17, 19, 23-30, 34-36, 38-41, 53, and 54 stand rejected under 35 U.S.C. § 102(e) as allegedly anticipated by U.S. Patent Application Publication No. 20020182586 ("Morris"). Applicants respectfully traverse.

In order to anticipate, a cited reference must teach each and every element of a claimed invention, either expressly or inherently. *See* MPEP § 2131. Furthermore, the fact that a certain result or characteristic *may* occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *See* MPEP § 2112(IV). Also, where a claimed element is not expressly disclosed in a cited reference, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that an allegedly inherent characteristic necessarily flows from the teachings of the cited prior art. See § MPEP 2112(IV). Moreover, "the missing descriptive material must be necessarily present in the thing described in the reference, and that it would be so *recognized* by persons of ordinary skill".

(Emphasis added.) *See Continental Can, Co. v. Monsanto Co.*, 948 F.2d 1264, 1268-1269 (Fed. Cir. 1991).

In making this rejection, the Examiner states that "Morris teaches identification of bioactive agents capable of modulating CA protein activity by adding a candidate agent to a cell comprising CA proteins to identify compounds with pharmacological activity that are able to enhance or interfere with the activity of CA protein". The Examiner points out that among the CA proteins disclosed by Morris is one encoded by SEQ ID NO:1223 which is 97% identical to SEQ ID NO:1 of the present application. *See* Office Action at page 8. However, this disclosure from Morris does not teach each and every element of amended claim 1, which specifies screening using a "polypeptide [that] has at least 95% amino acid sequence identity to SEQ ID NO:2 and *has nuclease activity* and determining a functional effect . . . by *measuring nuclease activity of the MRE11 polypeptide*". At a minimum, Morris does not disclose that SEQ ID NO:1223 encodes an MRE11 polypeptide and has nuclease activity as claimed in the present invention. At most, Morris discloses SEQ ID NO:1223 and the fact that this sequence is associated with carcinoma, with no further information on either the identity or function of the gene. Accordingly, Morris also does not disclose any assays that measure nuclease activity as specified by the claimed invention. Rather, Morris merely discloses generically that compounds may be identified by their ability to "enhance or interfere with the activity CA protein" with no disclosure of any specific assays, much less, a nuclease assay. Thus, Morris does not expressly teach each and every element of the claimed invention.

Neither does Morris disclose these claim elements inherently, contrary to the suggestion of the Examiner. The Examiner states that "it is assumed that since the polypeptide disclosed by Morris as SEQ ID NO: 1223 is identical to instant SEQ ID NO:2, and SEQ ID NO:2 has nuclease activity, then the Morris polypeptide also has nuclease activity". *See* Office Action at page 9. However, the Examiner's statement is not the standard used to determine inherency. As discussed in greater detailed below, among the factors to establish inherency is the requirement that "the missing descriptive material must be necessarily present in the thing described in the reference, and that it would be so *recognized* by persons of ordinary skill".

Because Morris is totally silent on the identity or function of SEQ ID NO:1223 (as it is with respect to every other sequence disclosed in this reference), one of skill in the art would have absolutely no basis for *recognizing* that SEQ ID NO:1223 has nuclease activity or that this activity could be used as a basis for screening for compounds. There mere fact that SEQ ID NO:1223 is expressed in carcinoma cells provides no clues as to its activity. In fact, there would be no way of recognizing that SEQ ID NO:1223 had nuclease activity short of cloning SEQ ID NO:1223 into an expression vector, expressing the encoded protein in a suitable host cell, purifying the protein, and assaying for a vast number of possible activities, one of which would be nuclease activity. This is not disclosed by Morris. All that is disclosed by Morris is that compounds may be identified by their ability to "enhance or interfere with the activity CA protein" with no disclosure of any specific assays. From the disclosure of Morris, one of skill in the art would not be able to recognize the limitation of claim 8, that specifies "determining a functional effect . . . by measuring nuclease activity of the MRE11 polypeptide". For this reason also, Morris does not provide an enabling disclosure of the claim elements of the present invention.

For the reasons above, Morris fails to teach each and every element of the claimed invention either expressly or inherently. Accordingly, Applicants respectfully request withdrawal of this ground for rejection.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,

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